

FOR THE DISTRICT OF DELAWARE

ROCHESTER DRUG CO-OPERATIVE, INC.,
on behalf of itself
and all others similarly situated,

Plaintiff, :

V.

ABBOTT LABORATORIES, :
FOURNIER INDUSTRIE ET SANTÉ, :
and LABORATORIES FOURNIER S.A., :

Defendants. :

Civil Action No.

JURY TRIAL DEMANDED

CLASS ACTION COMPLAINT

Plaintiff, Rochester Drug Co-operative, Inc. (“Plaintiff” or “RDC”) on behalf of itself and all others similarly situated, for its Class Action Complaint (“Complaint”) against defendants Abbott Laboratories (“Abbott”), and Fournier Industrie et Santé, and Laboratories Fournier S.A. (jointly “Fournier”) (collectively “Defendants”), alleges as follows based on: (a) personal knowledge; (b) the investigation of its counsel, including review of various pleadings and court orders in patent infringement litigation pending in this district; and (c) information and belief:

I. NATURE OF THE ACTION

1. This is a civil antitrust action seeking treble damages arising out of Defendants' unlawful exclusion of competition from the market for fenofibrate, a drug used to control levels of

cholesterol and triglycerides in humans, manufactured and sold by Defendants under the brand-name TriCor. As alleged below, Defendants used various acts and practices as part of an overall scheme to improperly maintain and extend Defendants' monopoly power in the market for fenofibrate, to the detriment of Plaintiff and the Class (as defined below).

2. Defendants began marketing a capsule version of their brand name drug TriCor in 1998. Defendants quickly garnered substantial revenues from the sale of TriCor capsules, generating over \$227 million in revenues in 2001. Defendants, however, recognized the substantial threat to their monopoly profits posed by the potential onset of competition from generic versions of TriCor. Because generics are generally much cheaper than brand-name drugs, and because, *inter alia*, drug substitution laws in every state encourage or require substitution of generic for brand-name drugs, generic products typically take the vast majority of the brand-name drug's sales directly and quickly after their introduction into the marketplace.

3. In response to the serious and known competitive threat posed by generics, Defendants hatched and implemented over several years a multifaceted scheme to maintain and extend their monopoly power in the fenofibrate market by improperly preventing and/or hindering generic manufacturers from effectively competing with TriCor. Defendants manipulated the complex distribution system for pharmaceutical products in the U.S., the patent laws, the Hatch-Waxman Amendments to the Federal Food, Drug, and Cosmetics Act (21 U.S.C. § 301-392) ("Hatch-Waxman"), and the courts to achieve their anti-competitive ends. In a nutshell, each time sales of TriCor were threatened by generic competition, Defendants acted to thwart generic entry by suing for patent infringement, in order to buy themselves time to destroy demand for the existing

version of TriCor (such as capsules) that was threatened by generic competition, and to convert demand to a new (but not improved) version of TriCor (such as tablets). Significantly, presented with prescriptions for the (new) TriCor, pharmacists could not automatically substitute generic versions of the (old) TriCor. Defendants thus destroyed a key avenue and mechanism of generic competition. By the time a generic form of TriCor capsules, for example, was launched, the generic's ability to compete had already been destroyed or severely damaged. The result: Defendants maintained their monopoly at the expense of all purchasers. That is not competition, but its antithesis.

A. The First Conversion

4. As stated, Defendants began by selling a capsule version of TriCor. Fearing the onset of generic competition, Defendants applied to the U.S. Food and Drug Administration ("FDA") for approval to market a tablet version of TriCor, which would be therapeutically equivalent and bioequivalent to the existing capsules. Moreover, the tablet offered no medical/clinical benefits over the existing capsules. Defendants nonetheless expended significant resources developing and seeking FDA approval for their new tablet formulation.

5. To destroy or cripple generic competition, Defendants took affirmative steps to (a) destroy the pre-existing demand for fenofibrate capsules, and (b) shift that demand to Defendants' new tablet formulation. This scheme was executed through, inter alia, the following acts:

a. Defendants purposely and intentionally sought to convert all TriCor prescriptions from the existing capsule formulation to the new tablet formulation by, inter alia, instructing their representatives to promote only the new tablet formulation, while discouraging

physicians from writing prescriptions for the older, capsule formulation.

b. To buy time to complete this conversion process, Defendants brought patent infringement suits in the Illinois District Court against the generic manufacturers. Defendants thereby took advantage of the Hatch-Waxman regulatory framework governing the marketing of generic drugs, which requires the FDA to stay approval of such drugs for up to 30 months when patent claims are asserted, regardless of the merit (or lack of merit) of such patent suits.

c. Defendants also took active steps to destroy any demand for the old capsule formulation that might have survived Defendants' sales tactics. For example, Defendants removed the capsule formulation from the National Drug Data File (a listing of drugs accessed by many participants in the drug distribution system), thereby hindering substitution of generics for any prescriptions written for the prior, branded capsule formulation. Once Defendants' market conversion strategy had succeeded, Defendants pulled the prior capsule formulation from the marketplace altogether.

6. As a result of Defendants' conduct, by the time generic manufacturers could begin selling their generic versions of fenofibrate capsules, the demand for fenofibrate capsules was virtually extinguished. Moreover, pharmacists and others could not legally substitute generic capsules when filling prescriptions for Defendants' new tablet formulation, even though the capsule and tablet products were therapeutically equivalent and bioequivalent.

7. Through their exclusionary scheme, Defendants were able to: (a) delay the first approval of a generic version of fenofibrate capsules (manufactured by Teva Pharmaceuticals, USA ("Teva")) until April 2002; and (b) almost completely shift the demand for fenofibrate from the

capsules to the tablets *before* April 2002, thereby precluding the generic manufacturers from effectively competing with Defendants. Indeed, even though generics typically capture well over 50% of the sales of their branded counterpart in their first year on the market, as a result of Defendants' conduct and scheme, Teva managed to capture only **5%** of the fenofibrate market.

B. The Second Conversion

8. Teva and another generic manufacturer, Impax Laboratories, Inc. ("Impax"), began developing generic versions of Defendants' (new) tablet formulation, but Defendants executed their "sue and switch" scheme once again. Defendants again sued for patent infringement to buy time to, once again, develop *another* TriCor tablet and switch demand from the prior tablet to the new, before the generic manufacturers could obtain FDA approval to sell their generic version of the prior tablet.

9. As part of this second "sue and switch" ploy, Defendants filed patent infringement suits before this Court, based on multiple patents that Defendants had been able to obtain while their first capsule-to-tablet conversion scheme was keeping generic competition at bay. These latest patent suits, before this Court, triggered multiple 30-month stays of approval of Teva's and Impax's proposed generic tablets. With the suits ongoing, Defendants sought and obtained FDA approval for their (new) tablet formulation of TriCor (to replace the prior tablet, that had replaced the capsule). This second tablet formulation (a) offered minimal (if any) benefits over the capsules, and (b) any supposed benefits were far outweighed by the increased cost of the new branded product relative to the cost of prospective generic competitors. Having successfully implemented their scheme yet again, Defendants withdrew the prior tablet formulation from the market altogether.

10. If Defendants were simply and solely interested in introducing an allegedly *better* TriCor product, they could have done so *without* taking the additional, affirmative steps, described above, to prevent generic versions of the prior formulation from being sold. However, by taking these affirmative steps, Defendants revealed that their goal was not to promote consumer welfare, but to block or disable generic competition and thereby preserve their own monopoly power. Defendants' ongoing scheme has been highly successful in thwarting generic competition: as of year-end 2004, Defendants maintained control of 95% of the fenofibrate sales in the United States, receiving over \$750 million in revenues.

11. As a result of their illegal scheme, Defendants: (1) illegally maintained their monopoly in the market for fenofibrate in the United States; (2) fixed, raised, maintained, and/or stabilized the price of fenofibrate at supra-competitive levels; and (3) overcharged Plaintiff and other direct purchasers of TriCor from Defendants by millions of dollars by depriving them of the benefits of competition from cheaper generic versions of TriCor.

12. Defendants' monopoly power, as described above, was maintained through willfully exclusionary conduct, as distinguished from growth or development as a consequence of a legally obtained valid patent, other legally obtained market exclusivity, a superior product, business acumen or historic accident.

13. As alleged in more detail below, Defendants violated § 2 of the Sherman Act through their entire, overarching scheme to improperly maintain and extend their market and monopoly power by foreclosing and/or delaying competition from lower-priced generic versions of TriCor.

II. JURISDICTION AND VENUE

14. This Complaint is filed and these proceedings are instituted under Section 4 of the Clayton Act, 15 U.S.C. § 15, to recover threefold damages and the costs of suit and reasonable attorneys' fees, for the injuries sustained by RDC and members of the Class of direct purchasers of TriCor from Defendants (defined below) resulting from violations by the Defendants, as hereinafter alleged, of Section 2 of the Sherman Act, 15 U.S.C. § 2. The jurisdiction of this Court is based upon 28 U.S.C. §§ 1331 and 1337(a), and 15 U.S.C. § 15.

15. Defendants transact business within this district, and the interstate trade and commerce, hereinafter described, is carried out, in substantial part, in this district. Venue, therefore, is appropriate within this district under 15 U.S.C. § 22, and 28 U.S.C. § 1391(b) and (c).

III. THE PARTIES

16. Plaintiff RDC is a drug wholesale cooperative located at 50 Jet View Drive, Rochester, New York, 14624. RDC purchased TriCor directly from Abbott during the Class Period as defined below, and was injured by the illegal conduct described herein.

17. Defendant Abbott is a company incorporated under the laws of the State of Illinois, with its principal place of business in Abbott Park, Illinois. Abbott develops, manufactures, and markets pharmaceuticals and related products in the United States.

18. Defendants Fournier Industrie et Santé, formerly known as Fournier Innovation et Synergie, and Laboratoires Fournier, S.A. are French corporations, with their principal places of business at 42 Rue de Longvie, 21300 Chenôve, France.

IV. CLASS ACTION ALLEGATIONS

19. Plaintiff brings this action on behalf of itself and, under Rule 23 of the Federal Rules of Civil Procedure, as representative of a Class defined as follows:

All persons or entities in the United States who purchased TriCor in any form directly from any of the Defendants at any time during the period April 9, 2002, through the present (the "Class").

Excluded from the Class are Defendants, and their officers, directors, management, employees, subsidiaries, or affiliates, and all federal governmental entities.

20. Members of the Class are so numerous that joinder is impracticable. Plaintiff believes the Class numbers in the hundreds. Further, the Class is readily identifiable from information and records in the possession of Defendants.

21. Plaintiff's claims are typical of the claims of the members of the Class. Plaintiff and all members of the Class were damaged by the same wrongful conduct by Defendants, *i.e.*, they paid artificially inflated prices for fenofibrate and were deprived of the benefits of competition from cheaper generic versions of TriCor as a result of Defendants' wrongful conduct.

22. Plaintiff will fairly and adequately protect and represent the interests of the Class. Plaintiff's interests are coincident with, and not antagonistic to, those of the Class.

23. Plaintiff is represented by counsel who are experienced and competent in the prosecution of class action antitrust litigation, and have particular experience with class action antitrust litigation in the pharmaceutical industry.

24. Questions of law and fact common to the members of the Class predominate over questions, if any, that may affect only individual Class members because Defendants have acted on

grounds generally applicable to the entire Class. Such generally applicable conduct is inherent in Defendants' wrongful conduct.

25. Questions of law and fact common to the Class include:

- a. whether Defendants maintained monopoly power by delaying generic entry;
- b. whether direct proof of Defendants' monopoly power is available, and if available, whether it is sufficient to prove Defendants' monopoly power without the need to also define a relevant market;
- c. to the extent a relevant market or markets must be defined, what that definition is or those definitions are;
- d. whether the activities of Defendants as alleged herein have substantially affected interstate commerce; and
- e. whether, and to what extent, Defendants' conduct caused antitrust injury to the business or property of Plaintiff and the members of the Class, and if so, the appropriate measure of damages.

26. Class action treatment is a superior method for the fair and efficient adjudication of the controversy, in that, among other things, such treatment will permit a large number of similarly situated persons to prosecute their common claims in a single forum simultaneously, efficiently, and without the unnecessary duplication of evidence, effort, and expense that numerous individual actions would engender. The benefits of proceeding through the class mechanism, including providing injured persons or entities with a method for obtaining redress on claims that it might not be practicable to pursue individually, substantially outweigh any difficulties that may arise in management of this class action.

27. Plaintiff knows of no difficulty to be encountered in the maintenance of this action that would preclude its maintenance as a class action.

V. FACTUAL ALLEGATIONS

A. **The Regulatory Structure Pursuant to Which Generic Substitutes for Brand-Name Drugs Are Approved**

28. Under the Federal Food, Drug, and Cosmetics Act (21 U.S.C. § 301-392), manufacturers who create a new, pioneer drug must obtain the approval of the FDA to sell the new drug by filing a New Drug Application (“NDA”). An NDA must include submission of specific data concerning the safety and effectiveness of the drug, as well as any information on applicable patents.

29. In 1984, Congress amended the Food, Drug and Cosmetics Act with the enactment of the Hatch-Waxman amendments, called the Drug Price Competition and Patent Term Restoration Act, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (“Hatch-Waxman”).

30. Hatch-Waxman simplified the regulatory hurdles for prospective generic manufacturers by eliminating the need for them to file a lengthy and costly NDA in order to obtain FDA approval. Instead, the FDA provides an expedited review process by which generic manufacturers may file an Abbreviated New Drug Application (“ANDA”).

31. The ANDA relies on the scientific findings of safety and effectiveness included by the brand-name drug manufacturer in the original NDA. The ANDA filer must demonstrate to the FDA that the generic drug it proposes to market is bioequivalent to the brand-name drug.

32. As a counter-balance to this abbreviated process for bio-equivalent generic drugs, Hatch-Waxman streamlined the process for a brand-name manufacturer to enforce its patents against infringement by generic manufacturers, and provided that, under certain conditions (as detailed below), the FDA could not grant a generic manufacturer final approval to market or sell a generic version of the brand-name drug for up to 30 months. This 30-month stay grants brand name drug

companies what is akin to a preliminary injunction without their having to meet the requirements of actually obtaining such an injunction. It also provides some period of time for patent litigation, if brought, to be litigated, although resolution of such litigation is not required before generic entry may occur. Rather, the generic entrant is allowed to make its own decision whether to launch if it has obtained final FDA approval but the litigation remains pending after the stay expires. The 30-month stay was not intended to allow brand name drug companies to simply buy time to switch demand from one formulation of their brand name drug to another, so that when a generic company is finally free of the stay, there are no sales left for it to win.

33. When the FDA approves a brand-name manufacturer's NDA, the FDA publishes any compound patents which (according to the brand-name manufacturer) claim the approved drug in a publication entitled the "Approved Drug Products with Therapeutic Equivalence Evaluations," known as the "Orange Book." 21 U.S.C. §355(j)(7)(A)(iii). In the case of method of use patents, the FDA lists in the Orange Book any patents which (according to the brand-name manufacturer) claim the approved drug for its approved method of use. In listing patents in the Orange Book, the FDA merely performs a ministerial act. The FDA does not check the facts supplied to it by the brand-name manufacturer, but trusts that the manufacturer will be truthful. After the NDA is approved, the brand-name manufacturer may list other new patents in the Orange Book as related to the NDA, if the brand-name manufacturer similarly certifies, inter alia, that the new patents claim either the approved drug (for compound patents) or that the patents claim the approved drug for approved methods of use (for method-of-use patents).

34. To obtain FDA approval of an ANDA (and thus the right to sell a generic version of a brand-name drug), a generic manufacturer must certify that the generic drug addressed in its ANDA will not infringe any patents listed in the Orange Book. Under Hatch-Waxman, a generic manufacturer's ANDA must contain one of four certifications:

- i. that no patent for the brand-name drug has been filed with the FDA (a "Paragraph I certification");
- ii. that the patent for the brand-name drug has expired (a "Paragraph II certification");
- iii. that the patent for the brand-name drug will expire on a particular date and the generic company does not seek to market its generic product before that date (a "Paragraph III certification"); or
- iv. that the patent for the brand-name drug is invalid or will not be infringed by the generic manufacturer's proposed product (a "Paragraph IV certification").

21 U.S.C. § 355(j)(2)(A)(vii).

35. If a generic manufacturer files only paragraph I, II, or III certifications, then it is able to take advantage of the expedited Hatch-Waxman approval process, and the FDA must act on the application within 180 days of receipt, unless both the FDA and the applicant agree to extend the deadline. 21 U.S.C. § 355(j)(5)(A).

36. If a generic manufacturer files a Paragraph IV certification claiming that a patent listed in the Orange Book is invalid or will not be infringed, a brand-name manufacturer has an opportunity to delay final FDA approval of the ANDA and the sale of the competing generic drug on the market. When a generic drug manufacturer files a paragraph IV certification with its ANDA, the generic manufacturer must promptly give notice of its certification to both the NDA-holder and the owner of the patent(s) at issue. If the NDA-holder initiates a patent infringement action against

the ANDA filer within 45 days of receiving the Paragraph IV certification, then the FDA may not grant final approval to the ANDA until the earlier of either: (a) 30 months; or (b) the issuance of a decision by a court that the patent is invalid or not infringed by the generic manufacturer's ANDA. 21 U.S.C. §355(j)(5)(B)(iii). Thus, merely by listing a patent in the Orange Book and filing a suit within 45 days of receiving a Paragraph IV certification regarding the listed patent, a brand-name drug manufacturer may delay when the generic drug is finally approved by the FDA, and when generic competition to the brand-name drug enters the market. During the pendency of the 30 month stay, the FDA may grant "tentative approval" to an ANDA applicant if the FDA determines that the ANDA would otherwise qualify for final approval but for the stay.

37. Because of the FDA rules alleged above, brand-name drug manufacturers have a strong financial incentive to: (a) list patents in the Orange Book, even if such patents are not eligible for listing; and (b) then sue any generic competitor that files an ANDA with paragraph IV certifications, even if the competitor's generic product does not actually infringe the listed patent(s), in order to delay final FDA approval of an ANDA for up to 30 months. For brand drugs with sizable sales, such as TriCor, every additional month that a generic is kept off the market means millions of dollars of additional profit to the brand company. In addition, prior to a recent change in the Hatch-Waxman regulations, brand companies could, and did, bring multiple infringement suits (based on multiple patents listed in the Orange Book) against a single ANDA, thereby obtaining independent 30-months stays associated with each suit. This practice was curtailed by a change in FDA regulations mandated by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, which, due to repeated abuses by brand manufacturers of the type described here,

limited brand manufacturers to a single stay of approval per ANDA. See 21 C.F.R. §§ 314.52, 314.95, 314.107(b)(3)(i)(A).

B. Generic Versions of Brand-Name Drugs are Significantly Less Expensive, and Take Significant Sales Directly From the Corresponding Brand-Name Versions

38. Typically, generic versions of brand-name drugs are priced significantly below the brand-name versions. Because of the price differentials, and other features of the pharmaceutical market such as drug substitution laws, generic versions are quickly substituted for their brand-name counterparts. In every state, pharmacists are permitted or required to substitute a generic product for a brand-name product unless the doctor has indicated that the prescription for the brand-name product must be dispensed as written. As more generic manufacturers enter the market, prices for generic versions of a drug predictably decrease even further because of competition among the generic manufacturers, and the loss of sales volume by the brand-name drug to the corresponding generic accelerates. Generic competition enables all members of the proposed Class to: (a) purchase generic versions of the drug at substantially lower prices; and/or (b) purchase the brand-name drug at a reduced price, or at a price that is lower than it would have been absent generic competition. However, until a generic manufacturer enters the market, there is no bioequivalent generic drug which competes with the brand-name drug, and therefore, the brand-name manufacturer can continue to charge supracompetitive prices profitably without losing all or a substantial portion of its brand-name sales. Consequently, brand-name drug manufacturers have a strong incentive and interest to use the tactics alleged above to delay the introduction of generic competition into the market.

C. TriCor

39. TriCor is used to reduce high-levels of low-density lipoprotein cholesterol (“LDL-C”), sometimes referred to as “bad cholesterol,” and triglycerides by promoting the dissolution and elimination of fat particles in the blood. TriCor also increases levels of high-density lipoprotein cholesterol (“HDL-C”), sometimes referred to as “good cholesterol,” and reduces LDL-C in patients with primary hypercholesterolemia (high bad cholesterol) or mixed dyslipidemia (high bad cholesterol and high triglycerides). TriCor is also effective at reducing triglycerides in patients with hypertriglyceridemia (high triglycerides). The active pharmaceutical ingredient in TriCor is fenofibrate.

40. Fenofibrate is a fibrate. Fibrates, statins, bile acid sequestrants, and niacin are categories of cholesterol-lowering drugs. Each of those categories addresses cholesterol conditions differently, each has different side effects, some more serious than others, and each has different efficacy profiles in (i) reducing LDL-C, (ii) raising HDL-C, and (iii) lowering triglycerides. A cholesterol-lowering drug from any of the four categories is not reasonably interchangeable with a drug from another of the categories.

41. Fibrate drugs include TriCor (fenofibrate), Atromid (clofibrate), and Lopid (gemfibrozil). Each fibrate drug is approved by the FDA for different indications, has different side effects, and is prescribed in specific and different circumstances that depend on the particular condition of the patient.

42. Because of the wide variations in side effects associated with clofibrate, gemfibrozil, and fenofibrate, differences in their approved indications, differences in how they are ingested, and

other differences, including those relating to their prescription and efficacy profiles, the three types of fibrate drugs are not reasonably interchangeable.

43. On January 23, 1990, the U.S. Patent and Trademark Office (the “PTO”) granted Defendant Fournier’s application for U.S. Patent 4,895,726 (the “‘726 patent”). In its ‘726 Patent, Fournier claims a dosage form of fenofibrate containing a co-micronized mixture of particles of fenofibrate and a solid surfactant. A solid surfactant is a surface-active agent that interacts with the surfaces of poorly soluble substances, such as fenofibrate, to help them dissolve. A micronized substance is one that has been reduced in size to the micron size range.

44. In 1997, Fournier granted Abbott an exclusive license to the ‘726 patent in the United States. Abbott submitted separate NDAs for three strengths of branded fenofibrate capsules it intended to market. The FDA approved the TriCor 67mg capsule NDA on February 9, 1998, and the TriCor 134 mg and 200 mg capsule NDAs on June 30, 1999. Defendants brought each of these products to market shortly after receiving FDA approval, and sales of the capsule rose quickly to top \$158 million by 2000, and \$277 million in 2001.

D. Defendants’ Wrongful Scheme to Delay Generic Competition

1. The Illinois Patent Litigation

45. On December 14, 1999, Novopharm Limited (which was subsequently acquired by Teva) filed an ANDA with the FDA requesting approval to market generic fenofibrate 67 mg capsules (the “Teva Capsule ANDA”) before the expiration of the ‘726 patent. The Teva Capsule ANDA was later amended by Novopharm to request approval to market generic fenofibrate 134 mg

and 200 mg capsules. In connection with the Teva Capsule ANDA, Novopharm certified under Paragraph IV that the proposed generic fenofibrate capsule did not infringe the '726 patent.

46. On May 9, 2000, Impax also filed an ANDA for fenofibrate capsules. Impax similarly sought approval to market its fenofibrate capsules prior to the expiration of the '726 patent, and accordingly certified under Paragraph IV that its product did not infringe the '726 patent, and duly and timely notified Abbott of its ANDA.

47. Defendants filed a series of infringement actions in the United States District Court for the Northern District of Illinois, against Teva (and its subsidiary, Novopharm) and Impax, alleging that the generic drug manufacturers had infringed the '726 patent under 35 U.S.C. §271(e)(2) (these suits, collectively, are referred to herein as the "Illinois Patent Litigation"). Under Hatch-Waxman, these suits – begun on or about April 7, 2000, August 18, 2000, and March 19, 2001, respectively – imposed 30-month stays on FDA approval of Teva's and Impax's generic products.

48. The FDA granted Impax tentative approval for Impax's fenofibrate capsules on February 20, 2002. However, Abbott's and Fournier's lawsuit had triggered the automatic 30-month stay under Hatch-Waxman, preventing FDA from granting final approval to Impax's capsule ANDA.

49. On March 19, 2002, the Illinois district court granted Teva's motion for summary judgment of non-infringement of the '726 patent in the Illinois Patent Litigation. In so doing, the Court construed various elements of the '726 patent, and concluded that Teva's generic fenofibrate capsule product did not literally infringe the patent. The court also held that Abbott and Fournier

were estopped from asserting a range of equivalents which might be construed to include Teva's generic fenofibrate product.

50. Teva subsequently received FDA approval to market its 67 mg, 134 mg and 200 mg fenofibrate capsules on April 9, 2002. While Teva received final approval for its 134 mg and 200 mg capsules on this date, and came to market shortly thereafter, as a result of a change in FDA regulations regarding the application of the Hatch-Waxman mandatory 30-month stay, Teva received only tentative approval for its 67 mg capsule. Thus, as a result of the stay, Teva was not able to launch its 67 mg capsule until September 3, 2002.

51. On March 26, 2003, the Illinois district court granted Impax's motion for summary judgment of non-infringement of the '726 patent based, inter alia, on Impax's assertion of collateral estoppel on the basis of the earlier summary judgment that had been granted in the Teva infringement actions. The FDA subsequently granted Impax final FDA approval to market its fenofibrate capsule products on October 28, 2003.

2. *The First Exclusionary Conversion*

52. As alleged above, Defendants knew that by merely filing the Illinois Patent Litigation within 45 days of receiving notice of the ANDA filings from Teva and Impax, they would, under the Hatch-Waxman regulatory framework, prevent the FDA from granting final approval to Teva and Impax for up to 30 months, regardless of whether Defendants' patent suits had any merit. Thus, even though Defendants lost the Illinois Patent Litigation, Defendants knew that by using the regulatory delay triggered by the mere filing of those actions, they could delay competition from Teva's and Impax's generic fenofibrate capsule products for up to 30 months.

53. In addition, Defendants used this delay to further suppress effective competition in the fenofibrate market by converting the demand in this market from capsules to tablets, and by destroying the remaining demand for fenofibrate capsules before the generic manufacturers could obtain FDA approval of their ANDAs.

54. Defendants implemented their scheme in steps:

- a. Defendants obtained FDA approval to market a TriCor tablet formulation (in 54 mg and 160 mg strengths) on September 4, 2001, while the Illinois Patent Litigation (over the capsules) was ongoing, and the 30-month stays of Teva's and Impax's generic fenofibrate capsules were still in effect. Importantly, the TriCor tablets offered no benefits to consumers because they contained the same drug as the existing TriCor capsules and were therapeutically and bioequivalent to the capsules. However, the tablets promised huge benefits to Defendants because there were no pending ANDAs seeking approval to market generic versions of the tablet.
- b. Defendants then stopped all new sales of TriCor capsules, and directed their sales force to sell only TriCor tablets in the future, and to pressure doctors not to write prescriptions for the capsule product.
- c. Defendants then removed the product code for the capsules from the National Drug Data File ("NDDF") maintained by First Data Bank, even though Defendants were not obligated to do so. Had the capsule code not been removed from the NDDF, physicians still could have written prescriptions for TriCor capsules, and such prescriptions could have been filled by any FDA-approved generic capsule version of TriCor. However, by removing the capsule code from the NDDF, Defendants rendered this code, to which generic capsules would have been compared,

obsolete. Because generic fenofibrate capsules could not be referenced to a TriCor capsule code, and because Abbott and Fournier removed TriCor capsules from the market, there was no longer a brand reference drug for generic fenofibrate capsules. Such removal hindered substitution of a generic fenofibrate product for a prescribed TriCor product.

d. Any attempt by Defendants to defend their conduct by claiming they wished to introduce an allegedly improved product, i.e. TriCor tablets, rings hollow because, as alleged herein, the tablets provide no material benefits to consumers that the capsules did not already provide. Moreover, even if the tablets had some benefit over the capsules (which they did not), such benefit could have been offered without eliminating demand for TriCor capsules and/or removing the capsule code from the NDDF. Had Defendants not acted to destroy the demand for capsules, doctors and patients would have more readily been able to weigh the relative benefits (and prices) of capsules versus tablets, and pick the one they preferred. Indeed, by withdrawing their capsules from the market, and impeding generic substitution for prescriptions of the branded capsules, Abbott acted against patients' interests by creating confusion and preventing patients who were using the capsules from refilling or renewing existing prescriptions with capsules (including cheaper generic capsules). If, in fact, Abbott were solely interested in providing additional medical options for patients, Abbott would not have taken the additional step of impeding the sale of generic capsules. Defendants' true goal, however, was to interfere with and impede, to the greatest extent possible, generic competition, to the detriment of TriCor purchasers.

55. Defendants invested significant resources in developing the 54 mg and 160 mg tablets. Then, Defendants invested significant resources in demonstrating to the FDA that the 54 mg

and 160 mg tablets are bioequivalent to the already-approved capsule formulations. Specifically, Defendants sought to convince the FDA that the tablets were bioequivalent to the capsules, and to obtain approval for a new indication for the tablets, which was for “raising HDL-C levels in adult patients with Frederickson Types IIa and IIb dyslipidemia.” In doing so, however, Defendants relied upon the same clinical studies that had been submitted in support of their NDA for the TriCor capsules. Thus, the studies submitted had been performed with the capsule formulations, not the tablet formulation. As the FDA Medical Officer reviewing Abbott’s 54 mg and 160 mg tablet NDA noted, “[t]hese studies, however, were conducted with the standard and micronized formulation of fenofibrate. Therefore, the approvability of this application relied on the demonstrated bioequivalence between the tablet and older formulations of fenofibrate.” Medical Officer’s Review of New Drug Application, August 30, 2000 (Mary H. Parks, M.D., Medical Officer) (available at http://www.fda.gov/cder/foi/nda/2001/21-203_Tricor_medr.pdf).

56. Thus, in obtaining approval for the 54 mg and 160 mg tablets, Abbott established that the bioavailability of two products did not differ significantly when the two products are given in similar dosages under similar conditions. After all of the expenses of researching and developing the 54 mg and 160 mg tablets, of submitting an NDA to the FDA in November 1999 and of supporting that application with multiple submissions to the FDA through September 2000, Defendants merely succeeded in getting approval for products that were deemed equivalent to products Defendants already had on the market.

57. Moreover, Defendants undertook the significant additional expenses of converting their manufacturing process to the tablet formulations. Defendants undertook the significant

additional expenses of “detailing” doctors and marketing the tablet formulations to health care entities with the goal of switching prescriptions and prescribing habits from the capsules to the bioequivalent tablets, which Defendants brought to the market at the same price as the capsule products.

58. Since Defendants were already marketing bioequivalent products, the process of developing, approving, launching, and converting the demand from the capsule to the tablet would not have been cost-justified *unless* the anti-competitive thwarting of generic competition is taken into account. Only this anticompetitive effect made Defendants’ switch from capsules to tablets worthwhile. It would not have occurred otherwise. Absent the expected harm to generic competition resulting from introduction of the 54 mg and 160 mg tablet products, Defendants would not have brought those products to market.

59. The purpose and effect of Defendants’ strategy was to destroy (and/or severely limit) generic competition that otherwise would have existed in sales of fenofibrate capsules. By engaging in this “sue and switch” scheme, Abbott and Fournier did not simply delay sales of generic fenofibrate capsules. Rather, they took additional steps that had the purpose and effect of impeding those generic capsules from ever meaningfully competing with TriCor products, even once Impax and Teva were legally permitted to begin sales, by destroying demand for fenofibrate capsules before Teva or Impax could enter the market.

60. As a result of Defendants’ exclusionary conduct, Teva and Impax were denied meaningful access to the normal mechanisms and processes in this country that are intentionally designed to encourage and foster substitution of cheaper generics for more expensive brand-name

drugs, and were denied the opportunity to effectively launch their generic fenofibrate products, and were excluded from the most efficient means of distributing their products. When Teva was finally able to launch its fenofibrate capsule (which remained bioequivalent to TriCor tablets but was much cheaper), Teva could capture only 5% of the fenofibrate market. By contrast, generics typically capture 40% to 80% (or more) of the brand's sales within the first year of launch. Thus, as a direct and proximate result of Defendants' overall scheme to monopolize, Defendants effectively destroyed generic competition that should have started in early 2002, and have improperly maintained a 95% share of the market for fenofibrate products; a share that would have eroded substantially in the face of price competition from lower-cost generic products but for Defendants' own anticompetitive conduct.

3. *The Delaware Patent Litigation*

61. Having successfully protected their blockbuster product (and monopoly profits) from generic competition, Defendants were quick to run the same play again when generic competitors again threatened. Defendants reflexively filed patent suits (before this Court) against generic competitors, regardless of the merit (or lack thereof) of such suits, in order to obtain the benefit of Hatch-Waxman's 30-month stay, while using the automatic delay to again convert demand in the fenofibrate market to a product not susceptible to generic substitution.

62. Apparently in reaction to Defendants' prior conversion of the fenofibrate market to TriCor tablets from capsules, Teva, on or around June 17, 2002, filed with the FDA an ANDA for generic fenofibrate 54 mg and 160 mg tablets (the "Teva Tablet ANDA"), along with a Paragraph IV certification that the ANDA did not infringe the '726 patent, or two additional patents that

Defendants had subsequently listed in the Orange Book as covering the TriCor tablets, U.S. Patent No. 6,074,670 (the “‘670 patent”), which issued on June 13, 2000, and U.S. Patent No. 6,277,405 (the “‘405 Patent”), which issued on August 21, 2001. On or around August 21, 2002, Teva gave notice to Defendants of the filing of the Teva Tablet ANDA and the Paragraph IV certifications made therein. Abbott received notice of Teva’s initial ANDA filing on August 26, 2002.

63. Teva subsequently amended its ANDA, on July 29, 2003 and December 17, 2003, respectively, by filing two additional Paragraph IV certifications, one for U.S. Patent 6,589,522 (the “‘552 patent”) and one for U.S. Patent 6,652,881 (the “‘881 patent”), shortly after Abbott listed each of these patents in the Orange Book as claiming TriCor. Teva duly served Abbott with notice of each of its certifications, which prompted additional infringement complaints filed within 45 days of this notice.

64. In three separate complaints filed in the United States District Court for the District of Delaware (later consolidated into a single action), Abbott alleged that Teva had infringed the five patents to which Teva had filed Paragraph IV certifications. The first complaint, filed on October 4, 2002, alleged infringement of the ‘726 Patent, the ‘670 patent, and the ‘405 patent; the second complaint was filed on August 29, 2003, alleging infringement of the ‘552 patent, and the third complaint was filed January 22, 2004, alleging infringement of the ‘881 patent.

65. By virtue of the filing of the first and second complaints, Defendants imposed two successive 30-months stays under Hatch-Waxman, thus barring FDA approval of Teva’s ANDA. The first 30-month stay was triggered by the first complaint filed (involving the ‘726, ‘670 and ‘405 patents), and it expired on February 26, 2005, or 30 months after Abbott received Teva’s first notice

letter. The second 30-month stay was generated by the second complaint filed involving the '552 patent, and is set to expire in February 2006. Because of the modifications to Hatch-Waxman made by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Abbott is not entitled to a third stay based on the third complaint for infringement of the '881 patent.

66. Similarly, Impax also sought to enter the fenofibrate market in the United States by filing an ANDA for fenofibrate tablets on or around December 2002. In connection with this ANDA, Impax submitted Paragraph IV certifications that the ANDA did not infringe the '726, the '670 and the '405 patents. As they had against Teva, Defendants sued Impax, asserting infringement of the '670 and the '405 patents. The filing of the initial infringement case, on January 23, 2003, triggered an automatic 30-month stay of approval of Impax's Tablet ANDA by the FDA. The issuance and Orange Book listing of the '552 patent resulted in an additional infringement case against Impax, and an additional 30 month stay. The listing of the '881 patent resulted in yet another suit against Impax, but again, as in the case of the suits against Teva, there was no additional 30-month stay associated with that infringement suit.

67. On March 5, 2004, the FDA granted tentative approval to Impax's and Teva's tablet ANDAs, which means that the FDA has determined that these generic products are bioequivalent to TriCor tablets of the same dosage strength, and that Teva and Impax have satisfied all the other regulatory requirements, such as demonstrating safety and efficacy, for sale of their fenofibrate product in the United States. The tentative approvals by the FDA would have been final approvals but for the successive 30-month stays resulting from Abbott's and Fournier's filing and maintenance of their patent infringement actions against Impax and Teva concerning the tablet ANDAs. Notably,

both Teva and Impax have represented to this Court that, absent the 30-month stays, they would have received final approval on March 5, 2004, and would have entered the market shortly thereafter.

68. The various infringement suits in Delaware against Teva and Impax were consolidated and/or coordinated before this Court (the “Delaware Patent Litigation”). The Delaware Patent Litigation was heavily litigated by and among Defendants, Teva and Impax, and trial was scheduled to begin on December 6, 2004. Defendants succeeded in getting this trial date pushed back six months, however, until June 6, 2005, through the filing of the subsequent infringement actions related to the ‘552 patent. Then, with less than a month to go before trial, Abbott and Fournier (having obtained the sought-after delay) sought voluntary dismissal of all the pending Delaware infringement actions.

4. The Second Exclusionary Conversion

69. Defendants’ outright abandonment of the Delaware Patent Litigation reveals their true motive for commencing these actions in the first place – to again provide Defendants time to convert the existing fenofibrate market to a formulation not threatened by generic competition. While the Delaware Patent Litigation was pending, Abbott and Fournier were planning another product switch, which was implemented in late 2004 (about eight months after the generic manufacturers had received tentative approval from the FDA for their tablet ANDAs).

70. While the Delaware actions against Impax and Teva were ongoing, Defendants, on November 5, 2004, obtained approval for a new NDA for a different formulation of TriCor tablets in 48 mg and 145 mg strengths. The latest TriCor tablets include the same medicine, and are

indicated for the same uses, as the prior TriCor tablets. However, by virtue of the new strengths, these latest tablets would not be susceptible to substitution from a generic version of the prior tablets.

71. In a familiar pattern, Abbott and Fournier then began marketing their latest TriCor tablets, replacing the 54 mg and 160 mg tablets. Once there was no more supply of Defendants' 54 mg and 160 mg tablets, Defendants removed the reference code in the NDDF for these formulations, once again impeding generic substitution.

72. Defendants' removal of the reference code in the NDDF for their 54 mg and 160 mg tablets also made it more expensive for any patients to use Impax's or Teva's fenofibrate tablets in the event that any doctors continue to write prescriptions for the 54 mg and/or 160 mg fenofibrate formulations. Patients will be forced to pay higher co-pay amounts for 54 mg or 160 mg fenofibrate tablets, even if sold by a generic company, when there is no brand reference code for Abbott's and Fournier's TriCor 54 mg or 160 mg tablets in the NDDF, than they would be required to pay for generic tablets if Abbott and Fournier maintained the brand reference in the NDDF. Without a reference code in the NDDF for TriCor R 54 mg or 160 mg tablets, Impax's and Teva's tablets would be treated as branded products rather than a generic products, which, in turn, triggers mechanisms that insurers have in place requiring higher co-payments for branded products. These same mechanisms would have also burdened and hindered Teva's and Impax's capsule products, when Defendants acted to remove the TriCor capsule code from the NDDF.

73. Based on the previous experience of the switch from the capsule to tablet, it is likely that the supply of Abbott's and Fournier's 54 mg and 160 mg tablets will virtually disappear approximately six months after the date Abbott and Fournier stopped marketing this formulation.

74. As alleged above, but for Abbott's and Fournier's anticompetitive conduct, the branded tablet formulations likely never would have been introduced (because generic capsules would have dominated the market before the tablets could be launched, and the tablets offered no material benefits over the capsules). Alternatively, the generic manufacturers would have started selling generic fenofibrate 54 mg and 160 mg tablets shortly after March 5, 2004, the date on which FDA granted tentative approval (and but for Abbott and Fournier's conduct would have granted final approval) to Impax's and Teva's tablet ANDAs. Abbott and Fournier received approval for their latest tablet formulation NDA only in November of 2004, and could not have implemented their efforts to switch the market until that time. Thus, but for Abbott's and Fournier's conduct, Impax and Teva would have started selling their generic fenofibrate tablets eight months before Abbott and Fournier could have begun to (once again) convert the market to their latest TriCor formulation.

75. Had Teva and Impax been able to start selling their tablets in March of 2004, the generic manufacturers would have successfully entered the fenofibrate market and would have captured significant sales. Impax and Teva also would have been able to maintain demand for the 54 mg and 160 mg tablets even if Abbott and Fournier subsequently removed the reference for TriCor 54mg or 160 mg tablets from the NDDEF. This is because, if a generic fenofibrate formulation is available on the market before Abbott and Fournier were able to complete their switch, there would continue to be pressure from the managed care industry for patients to continue to be prescribed the 54 mg and 160 mg tablets. If, however, a generic product does not get to market before the switch is completed, the managed care industry will not exert pressure to return patients to the 54 mg and 160 mg tablets once those generic tablets become available. By taking actions that

have postponed the launch date for Teva's and Impax's fenofibrate tablets, Defendants have again prevented Teva and Impax from utilizing the most efficient and practical means of distributing their generic drug products, and have again preserved their monopoly profits at the expense of purchasers.

76. Abbott's and Fournier's conduct is intended to prevent, and likely will prevent, new prescriptions for the 54 mg and 160 mg fenofibrate tablet formulations from being written. Defendants' conduct also will encourage prescriptions for the 54 mg and 160 mg fenofibrate tablets to be converted to their latest tablet formulations. In the future, this will mean that a pharmacist will not be presented with a prescription that would allow for substitution with a generic version of the 54 mg and 160 mg tablet formulations.

77. In connection with their NDAs for TriCor capsules and for TriCor 54 mg and 160 mg tablets, Abbott and Fournier submitted data to the FDA showing that those products are safe and effective. By approving Defendants' NDAs for those products, the FDA determined that those products are, among other things, safe and effective. Importantly, Abbott and Fournier have not disclosed any health or safety concerns, or any other concerns, with their capsule formulation of TriCor that justified pulling the product from the market and removing it from the NDDF. Similarly, Abbott and Fournier have not disclosed any health or safety concerns, or any other concerns, with their 54 mg or 160 mg tablet formulations of TriCor that justifies pulling those products from the market and removing them from the NDDF. In fact, Defendants' "new" product introductions were simply a tactic to maintain their monopoly in sales of fenofibrate products in the United States and to preclude Teva and Impax from the \$750 million fenofibrate market.

E. Effect on Interstate Commerce

78. At all material times, TriCor, manufactured and sold by Defendants, was shipped across state lines and sold to customers located outside its state of manufacture.

79. During the relevant time period, in connection with the purchase and sale of TriCor, monies as well as contracts, bills and other forms of business communication and transactions were transmitted in a continuous and uninterrupted flow across state lines.

80. During the relevant time period, various devices were used to effectuate the illegal acts alleged herein, including the United States mail, interstate and foreign travel, and interstate and foreign telephone commerce. The activities of Defendants, as charged in this Complaint, were within the flow of, and have substantially affected, interstate commerce.

F. Monopoly Power

81. Through the anticompetitive conduct alleged herein, Defendants were able to charge supracompetitive prices for fenofibrate, and thus, by definition, maintained monopoly power with respect to fenofibrate sold in the United States. To the extent that Plaintiffs are legally required to prove monopoly power circumstantially by first defining a relevant product market, Plaintiffs allege that the relevant product market is all fenofibrate products – i.e., TriCor (in all its forms and dosage strengths), and bioequivalent fenofibrate products. There are no reasonably interchangeable drug products that are available to prescribing physicians for the indications for which fenofibrate is prescribed. For the entire period relevant to this case, Defendants have been able to profitably maintain the price of their branded fenofibrate products well above competitive levels.

82. The relevant geographic market is the United States and its territories.

83. Defendants' market share in the relevant market is and was 100% at all times prior to the sale of Teva's fenofibrate capsules in the United States, and has been at least 95% thereafter.

84. Defendants' actions are part of, and in furtherance of, the illegal monopolization alleged herein, were authorized, ordered or done by Defendants' officers, agents, employees or representatives while actively engaged in the management of Defendants' affairs.

85. Defendants' illegal acts to prevent the introduction and/or dissemination into the U.S. marketplace of any generic version of TriCor resulted in Plaintiffs and the Class paying more than they would have paid for fenofibrate, absent Defendants' illegal conduct.

G. Effects on Competition and Damages to Plaintiffs and Class

86. Defendants' exclusionary conduct has delayed or prevented the sale of generic fenofibrate in the United States, and unlawfully enabled Defendants to sell TriCor at artificially inflated prices. But for Defendants' illegal conduct, generic competitors would have been able to successfully market generic versions of TriCor capsules by at least April 9, 2002, and additional generic competitors would have entered the market thereafter. Moreover, to the extent that demand for 54mg and 160mg fenofibrate tablets would have existed but for Defendants' illegal conduct, generic competitors would have begun marketing generic versions of TriCor tablets by at least March 5, 2004, and additional generic competitors would have entered the market thereafter.

87. Defendants' pattern and practice of delaying generic entry while simultaneously changing product formulations and discontinuing existing products and delisting the drug from the NDDF, as alleged above, is exclusionary and unreasonably restrains competition. To the extent that Abbott and Fournier have any valid business purpose for their conduct, that purpose could be served

by means that are less restrictive of competition, and would at all events be outweighed by the anticompetitive effects of their conduct. Among other things, Abbott and Fournier could have launched a new tablet product without taking affirmative steps to destroy the demand for the existing capsule product. Abbott's and Fournier's conduct has allowed, and continues to allow, them to maintain a monopoly and exclude competition for TriCor, to the detriment of all fenofibrate purchasers, including Plaintiff, members of the Class, and consumers. Accordingly, the anticompetitive effects of Defendants' conduct clearly outweigh the purported procompetitive benefits (if any) of such conduct.

88. Similarly, Defendants cannot justify their conduct with any supposed consumer benefit, as the enormous cost savings offered by generic drugs outweigh any supposed benefit from the new formulations of TriCor, which benefits are illusory and/or could have been obtained without taking affirmative steps to destroy demand for fenofibrate capsules. Defendants' exclusionary motive is also illustrated by their willingness to sacrifice profits as part of the market switch strategy: Defendants' decision to incur the extra costs necessary to change formulations was economically rational only if the change promised to exclude or hinder generic competition. Defendants' introduction of the 54 mg and 160 mg tablets, which were bioequivalent to Defendants' capsules, and which relied upon the same clinical studies as were used to support the capsule NDA, was itself anti-competitive. But for the impact on generic competition, Defendants would not have invested the resources necessary to bring the 54 mg and 160 mg tablets to the market. But for the impact on generic competition, it would not have been economically rational to invest in the process of developing the bioequivalent tablet formulation, seeking FDA approval of that formulation, changing

the manufacturing process, and engaging in significant marketing efforts to switch the market from capsules to the equivalently priced tablets.

89. If manufacturers of generic fenofibrate had been able to enter the marketplace and effectively compete with Defendants earlier, as set forth above, Plaintiff and other members of the Class would have substituted lower-priced generic fenofibrate for the higher-priced brand-name TriCor for some or all of their fenofibrate requirements, and/or would have received discounts and/or a lower price than they would have otherwise on some or all of their remaining TriCor purchases.

90. During the relevant period, Plaintiff and other members of the Class purchased substantial amounts of TriCor directly from Defendants. As a result of Defendants' illegal conduct alleged herein, Plaintiff and other members of the Class were compelled to pay, and did pay, artificially inflated prices for their fenofibrate requirements. Plaintiff and the other Class members paid prices for fenofibrate that were substantially greater than the prices that they would have paid absent the illegal conduct alleged herein, because: (1) class members were deprived of the opportunity to purchase lower-priced generic fenofibrate instead of expensive brand-name TriCor; (2) Class members paid artificially inflated prices for generic fenofibrate and/or (3) the price of branded TriCor was artificially inflated by Defendants' illegal conduct. As a consequence, Plaintiff and other members of the Class have sustained substantial losses and damage to their business and property in the form of overcharges.

COUNT I

**Monopolization in Violation of Section 2 of the Sherman Act:
Defendants Delayed And Excluded Competition Through An Overarching Scheme**

91. Plaintiff refers to, and incorporates herein, the allegations above in ¶¶ 1–90.

92. Defendants used various willful and exclusionary means as part of an overall scheme described herein to improperly maintain and extend their monopoly power in the fenofibrate market, as detailed above.

93. The goal, purpose and/or effect of Defendants' scheme was to prevent, delay, and/or minimize the success of the entry of generic fenofibrate competitors which would have sold generic fenofibrate in the United States at prices significantly below Defendants' prices for TriCor, which would have effectively caused the average market price of fenofibrate to decline dramatically.

94. The goal, purpose and/or effect of Defendants' scheme was also to maintain and extend Defendants' monopoly power with respect to fenofibrate. Defendants' illegal scheme to prevent, delay, and/or minimize the success of the introduction into the United States marketplace of any generic version of TriCor enabled Defendants to continue charging supra-competitive prices for fenofibrate without a substantial loss of sales.

95. As a result of Defendants' illegal scheme, Plaintiff and the Class paid more than they would have paid for fenofibrate, absent Defendants' illegal conduct. But for Defendants' illegal conduct, competitors would have begun marketing generic versions of TriCor well before they actually did, and/or would have been able to market such versions more successfully.

96. If manufacturers of generic fenofibrate had been able to enter the market and compete with Defendants in a full and timely fashion, Plaintiff and other Class members would have substituted lower-priced generic fenofibrate for the higher-priced brand-name TriCor for some or all of their fenofibrate requirements, and/or would have received lower prices on some or all of their remaining TriCor purchases.

97. During the relevant period, Plaintiff and the other Class members purchased substantial amounts of TriCor directly from Defendants. As a result of Defendants' illegal conduct alleged herein, Plaintiff and the other Class members were compelled to pay, and did pay, artificially inflated prices for their fenofibrate requirements. Plaintiff and all of the other class members paid prices for fenofibrate that were substantially greater than the prices that they would have paid absent the illegal conduct alleged herein, because: (1) class members were deprived of the opportunity to purchase lower-priced generic fenofibrate instead of expensive brand-name TriCor; (2) class members were forced to pay artificially inflated prices for generic fenofibrate and/or (3) the price of branded TriCor was artificially inflated by Defendants' illegal conduct.

98. Defendants' scheme was, in the aggregate, an act of monopolization undertaken with the specific intent to monopolize the market for fenofibrate in the United States, in violation of Section 2 of the Sherman Act, 15 U.S.C. § 2.

VI. DEMAND FOR JURY

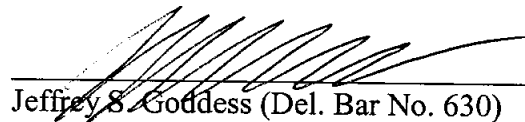
99. Plaintiff demands trial by jury on all issues so triable.

VII. PRAYER FOR RELIEF

WHEREFORE, Plaintiff, on behalf of itself and the Class, respectfully prays that:

- (i) The Court determine that this action may be maintained as a class action pursuant to Rule 23 of the Federal Rules of Civil Procedure, and direct that reasonable notice of this action, as provided by Rule 23(c)(2) of the Federal Rules of Procedure, be given to the Class;
- (ii) The acts alleged herein be adjudged and decreed to be an unlawful restraint of trade in violation of Section 2 of the Sherman Act;
- (iii) Each member of the Class recover three-fold the damages determined to have been sustained by each of them, and that joint and several judgment be entered against Defendant in favor of the Class;
- (iv) The Class recover their costs of suit, including reasonable attorneys' fees as provided by law; and
- (v) The Class be granted such other, further and different relief as the nature of the case may require or as may be determined to be just, equitable, and proper by this Court.

Dated: June 2, 2005


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